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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 98

[Docket No. APHIS-2008-0043]

RIN 0579-AD20

Importation of Live Swine, Swine Semen, Pork, and Pork Products; Estonia, Hungary, Slovakia, and Slovenia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: APHIS is amending the regulations governing the importation of certain animal embryos and animal semen by removing one of the conditions for the importation of swine semen from the APHIS-defined European CSF region, a region of Europe that we recognize as a single low-risk region for classical swine fever. We have determined that the 40-day holding period for swine semen and donor boars after the collection of swine semen is unnecessary. We are also announcing the addition of Estonia, Hungary, Slovakia, and Slovenia to the APHIS-defined European CSF region, the addition of Estonia, Slovakia, and Slovenia to the list of regions APHIS considers free of swine vesicular disease (SVD), and the addition of Slovakia and Slovenia to the list of regions APHIS considers free of foot-and-mouth disease (FMD) and rinderpest. These actions will relieve some restrictions on the importation into the United States of certain animals and animal products from those regions, while continuing to protect against the introduction of CSF, SVD, FMD, and rinderpest into the United States.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Mr. Donald Link, Import Risk Analyst,  
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#### SUPPLEMENTARY INFORMATION:

##### Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country.

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including classical swine fever (CSF), foot-and-mouth disease (FMD), swine vesicular disease (SVD), and rinderpest. These are dangerous and communicable diseases of ruminants and swine.

The regulations in 9 CFR part 98 govern the importation of animal germplasm to prevent the introduction of contagious diseases of livestock and poultry into the United States. Subparts A and B of part 98 apply to animal embryos, and subpart C (§§ 98.30 through 98.38) applies to animal semen.

Sections 94.0, 94.9, and 94.10 of the regulations provide for the listing of regions of the world that APHIS considers free of, or low-risk for, CSF. The APHIS-defined European CSF region, consisting of countries of Europe that we currently recognize as a single region with regard to CSF, is currently the only region we consider low-risk for CSF. Sections 94.24 and

98.38 specify restrictions necessary to mitigate the risk of introducing CSF into the United States via pork, pork products, live swine, and swine semen from that region.

Section 94.12 of the regulations provides for the listing of regions that are declared free of SVD, and § 94.13 of the regulations provides for the listing of regions that have been determined to be free of SVD, but that are subject to certain restrictions because of their proximity to or trading relationships with SVD-affected regions.

Section 94.1 of the regulations provides for the listing of regions of the world that are declared free of rinderpest or free of both rinderpest and FMD. Section 94.11 of the regulations provides for the listing of regions that have been determined to be free of rinderpest and FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions.

On February 11, 2011, we published in the Federal Register a proposed rule<sup>1</sup> (76 FR 7721-7731, Docket No. APHIS-2008-0043) to add Estonia, Hungary, Slovakia, and Slovenia to the APHIS-defined EU CSF region. (NOTE: In a final rule published on November 10, 2011 [76 FR 70037-70040, Docket No. APHIS-2009-0093], APHIS changed the term “APHIS-defined EU CSF region” to “APHIS-defined European CSF region.”) We also proposed to add Estonia, Slovakia, and Slovenia to the list of regions we consider free of SVD and to add Slovakia and Slovenia to the list of regions considered free of FMD and rinderpest. Finally, we proposed to amend § 98.38 to remove the 40-day post-collection holding period for swine semen and donor boars prior to export of swine semen from the APHIS-defined EU CSF region to the United States. Except for semen collected from swine in Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom, we required that, before swine semen may be exported

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<sup>1</sup> To view the proposed rule, supporting documents, or the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0043>.

to the United States, the semen and donor boars be held at the semen collection center for at least 40 days following collection of the semen, and that the donor boars, along with all other swine at the semen collection center, exhibit no clinical signs of CSF.

We solicited comments concerning the proposed rule for 60 days ending April 12, 2011, and received three comments by that date. They were from an organization representing the pork industry within the United States and two private citizens. These comments are discussed below by topic.

#### Comments Regarding Evaluations of Animal Disease Status in Support of the Proposed Rule

In order for APHIS to evaluate the CSF, SVD, FMD, and/or rinderpest status of their respective countries, the Governments of Estonia, Hungary, Slovakia, and Slovenia provided us with information regarding the authority, organization, and infrastructure of the official veterinary services in their countries; the status of their countries and adjacent regions with regard to the disease(s) under evaluation; the degree to which their countries are separated from regions of higher risk; and livestock demographics and marketing practices. They also provided information regarding vaccination against the disease(s) of interest; the extent of active disease control programs for the diseases; movement controls and biosecurity for movement from higher risk regions; disease surveillance; diagnostic laboratory capabilities; and emergency response capacity.

Based on this information, a site visit to each country, and other publicly available information, APHIS prepared an evaluation regarding the CSF and SVD status of Estonia; an evaluation regarding the CSF status of Hungary; an evaluation regarding the CSF, SVD, FMD, and rinderpest status of Slovakia; and an evaluation regarding the CSF, SVD, FMD, and

rinderpest status of Slovenia. The conclusions in these evaluations led us to issue the proposed rule.

One commenter stated that, since the evaluations were finalized, FMD has been detected in Bulgaria. The commenter stated that European Commission<sup>2</sup> (EC) regulations regarding FMD are adequate to monitor, detect, control, and eradicate the disease in Member States, but also suggested that the introduction of FMD into Bulgaria was due to that country's failure to adhere to EC regulations regarding passive surveillance and disease reporting. The commenter suggested that this failure may be indicative of the potential for similar failures in passive surveillance and disease reporting in Estonia, Hungary, Slovakia, and Slovenia. Accordingly, the commenter requested that we not finalize the proposed rule until the EC finishes its review of the outbreaks in Bulgaria and implements corrective actions to make certain that all EU Member States are conducting adequate passive surveillance for FMD, and until we prepare new evaluations to take those additional measures into consideration insofar as they pertain to Estonia, Hungary, Slovakia, and Slovenia.

Because Bulgaria is an EU Member State, and thus eligible for intra-Community trade, APHIS concurs with the commenter that the outbreaks of FMD in Bulgaria are an issue of concern, and accordingly has been monitoring the disease situation in that country. The EC has provided APHIS officials stationed within the EU with regular updates regarding the outbreaks, and has posted updated outbreak information for the general public at the Web site for its Standing Committee on the Food Chain and Animal Health.

To summarize, on January 4, 2011, FMD was detected in a single wild boar in Bulgaria. Since then, there have been multiple outbreaks, primarily along the border between Bulgaria and

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<sup>2</sup> The European Commission is the EU institution responsible for representing the EU as a whole. It proposes legislation, policies, and programs of action and implements decisions of the EU Parliament and Council.

Turkey. In response to the outbreaks, Bulgarian officials implemented measures to delineate the scope of the outbreaks and to control and eradicate the disease in domestic livestock within the country.

To date, we have no evidence that domestic ruminant populations in other Member States should be considered exposed to or potentially affected with FMD. Indeed, the EC recently reduced the restricted area of Bulgaria that is covered by EC measures designed to prevent the spread of FMD. Furthermore, as the commenter conceded, current EC regulations, if adhered to, are sufficient to detect, control, and eradicate FMD whenever it occurs within a Member State.

Based on the information provided to us by Estonia, Hungary, Slovakia, and Slovenia, as corroborated by our site visits to the countries, we believe the countries have implemented the relevant EC legislation regarding surveillance for CSF, SVD, FMD and/or rinderpest, and that producers in these countries can recognize clinical signs of the diseases and report any such potentially affected animals in a timely manner. Therefore, we are not granting the commenter's request. We will, however, continue to closely monitor the current FMD situation in Bulgaria.

The same commenter asserted that our conclusion--that live swine, swine semen, pork, and pork products may safely be imported into the United States from Estonia, Hungary, Slovakia, and Slovenia, subject to the restrictions of the regulations--was based on the absence of FMD within the EU. Accordingly, the commenter requested that we not finalize the proposed rule until we prepare new assessments that take into consideration the presence of FMD in Bulgaria. Similarly, another commenter asked what information had been taken into consideration in reaching our conclusions.

As noted above, our conclusions were based on an evaluation of the information supplied by Estonia, Hungary, Slovakia, and Slovenia regarding the authority, organization, and

infrastructure of the veterinary services in their countries; the status of their countries and adjacent regions with regard to the disease(s) under evaluation; the degree to which their countries are separated from regions of higher risk; livestock demographics and marketing practices; vaccination against the disease(s) of interest; the extent of active disease control programs for the diseases; movement controls and biosecurity for movement from higher risk regions; disease surveillance; diagnostic laboratory capabilities; and emergency response capacity. Cumulatively, this information demonstrated the countries' compliance with existing EC regulations, which mitigate the likelihood that CSF, SVD, FMD, and/or rinderpest will be introduced into the domestic swine populations within the countries, and led to our conclusion that, by applying the restrictions of the regulations, swine, swine semen, pork, and pork products may safely be imported from Estonia, Hungary, Slovakia, or Slovenia into the United States.

In addition, we note that Estonia and Hungary have been listed under § 94.11 since 2002 and 1994, respectively, as regions that are free of FMD but subject to certain restrictions because of their trading relationships with FMD-affected countries.

A commenter pointed out that, in our evaluation of Slovakia with regard to CSF, SVD, FMD, and rinderpest, we noted that Slovakian veterinary inspectors are not stationed at every border crossing into the country to inspect passenger baggage. The commenter also pointed out that, at those crossings where inspectors are stationed, there are certain hours throughout the day when the crossings are unattended by the inspectors. The commenter suggested that Slovakia needed to position inspectors at all ports of entry and needed to expand inspection coverage beyond normal working hours. Additionally, the commenter pointed out that, in the evaluation of Hungary with regard to CSF, we noted that posters alerting travelers to prohibitions on the importation of certain animal products in personal baggage were not displayed at several of the

border inspection posts (BIPs) in the country. As a result, the commenter questioned our basis for concluding that the risk posed by the importation of contaminated animal products in passenger baggage is sufficiently mitigated at ports of entry into these two countries and stated that we had not provided sufficient evidence to support this conclusion.

Slovakia has stationed inspectors at the busiest border crossings during those hours of the day when the most travelers enter the country through these border crossings. Slovakia's actions are consistent with EC regulation (EC) 206/2009, which allows a country to utilize a risk-based approach to establishing controls at ports of entry to minimize the likelihood that animal products imported into the country in personal baggage will serve as fomites for diseases affecting livestock.<sup>3</sup> Our determination that the risk posed by the importation of contaminated animal products in passenger baggage is sufficiently mitigated at ports of entry into Slovakia was based on this consistency, on the physical and technological infrastructure of the BIPs, on the apparent volume of passenger baggage entering through these BIPs at the time of our site visit, on the number of inspectors employed at the BIPs and the training afforded to these inspectors, and on the auditing and monitoring of inspections conducted by the State Veterinary and Food Administration of the Slovak Republic, the veterinary authority for Slovakia.

Requiring Slovakia to station inspectors at all ports of entry and beyond normal business hours would be significantly more stringent than EC standards, and is not necessary to reach a determination that the risk that contaminated products will enter the country in passenger baggage has been sufficiently mitigated.

We agree with the commenter that posters alerting travelers to prohibitions and restrictions on the importation of animal products in personal baggage help to reduce the risk that

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<sup>3</sup> Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:077:0001:0019:EN:pdf>. Accessed on May 6, 2011.



contaminated products may enter Hungary in such baggage, and should be fully incorporated into their controls at all ports of entry into the country. However, the presence or absence of such posters was not our sole consideration in determining whether Hungary has sufficiently mitigated the risk that contaminated products will enter Hungary in passenger baggage. As we did for Slovakia, we evaluated the physical and technological infrastructure of the BIPs, the number of inspectors stationed at BIPs and other border crossings, the degree to which these inspectors have been trained to inspect personal baggage, the volume of passenger baggage entering the country, the number of random and targeted luggage searches, and the reporting and monitoring requirements governing these inspections that have been imposed by the veterinary authority for Hungary. Collectively, the results of these evaluations led us to conclude that the risk that contaminated products will enter Hungary in passenger baggage is sufficiently mitigated.

The same commenter pointed out that, in our evaluation of Slovakia, we noted that the majority of swine holdings in the country are small, and that biosecurity on those farms is somewhat lacking in comparison to biosecurity standards at larger, commercially maintained premises within the country. The commenter further pointed out that we conceded that these swine have more of a risk of exposure to CSF, SVD, FMD, and rinderpest, and that the primary mitigation we cited was the lack of movement of swine from these facilities or the movement only for custom slaughter. The commenter suggested that access to a lucrative market such as the United States could change these production practices, and increase the likelihood that such producers will instead choose to export their swine. The commenter suggested that this, in turn, could increase the risk that swine or pork products contaminated with CSF, SVD, FMD, or rinderpest virus could be imported to the United States from Slovakia. Accordingly, the

commenter requested that we prepare a new evaluation that takes this possible change in marketing practices into consideration.

We do not consider a new evaluation to be necessary. Such producers have had access to foreign markets within the EU and throughout the world for an extended period of time, and have not changed their marketing practices. Moreover, even if these marketing practices were to change in the manner suggested by the commenter, all such animals and animal products would still be subject to EC regulations and U.S. import requirements, which we consider to be effective in mitigating the risk of importation of affected swine and/or contaminated products into the United States.

Comment Regarding the Removal of the 40-Day Post-Collection Holding Period for Swine Semen Imported from the APHIS-Defined EU CSF Region

As noted above, we proposed to remove one of the conditions for the importation of swine semen from the APHIS-defined EU CSF region, which required, with limited exceptions, that before swine semen may be exported to the United States, the semen and donor boars be held at the semen collection center for at least 40 days following collection of the semen, and that the donor boars, along with all other swine at the semen collection center, exhibit no clinical signs of CSF. We proposed to remove this requirement on the grounds that, since we established the requirement, the EC has modified its regulations to strengthen controls for CSF introduction or dissemination via infected germplasm, and we have strengthened our own regulations governing the importation of swine semen from a CSF-affected region. We also noted that the majority of swine semen used for artificial insemination is less than 5 days old and the current prohibition, therefore, was burdensome to exporters and inhibited trade.

One commenter stated that, in the event of an outbreak of CSF, it often takes several days to conduct an epidemiological investigation. The commenter stated that, if we were to remove the requirement, there is a possibility that swine semen contaminated with CSF virus could be imported into the United States and used to inseminate domestic sows before the scope of the outbreak is delineated and a prohibition on the importation of swine semen from the affected country into the United States is put in place. The commenter asked that APHIS provide to the U.S. pork industry a detailed response plan for exposure of U.S. swine to fresh semen that is epidemiologically linked to a CSF case in the exporting country.

Current EU regulations specify conditions for approval and supervision of artificial insemination centers, pre-admission quarantine and testing of boars, serologic testing for CSF, clinical observation of donor boars, and movement controls and epidemiologic investigation procedures in the event that an outbreak of CSF is suspected. The movement controls include restrictions on the movement of swine semen, and epidemiologic investigations may include inspections of swine semen collection facilities. Because of these interlocking safeguards and our own regulations and policies, we consider the possibility that CSF virus-contaminated germplasm will be exported to the United States from a country within the APHIS-defined European CSF region to be remote, even with the removal of the 40-day holding period.

In the unlikely event that the scenario proposed by the commenter comes to pass, we would take actions consistent with the outbreak of any foreign animal disease within the United States. In collaboration with State animal health officials and other emergency response partners, we would determine the scope of the outbreak, identify potentially affected animals, place the appropriate restrictions or prohibitions on the movement of those animals, implement

the mitigation measures necessary to prevent further disease spread, and conduct cleaning and disinfection of affected premises and articles.

#### Lists of Regions Removed from the CFR

When we published the proposed rule for this action in February 2011, the countries included in the APHIS-defined EU CSF region (now APHIS-defined European CSF region), and foreign regions considered free of or affected with various animal diseases and pests, including CSF, SVD, rinderpest, and FMD, were listed in our animal and animal product import regulations in 9 CFR parts 92, 93, 94, 96, and 98. In a final rule<sup>4</sup> published in the Federal Register on January 10, 2012 (77 FR 1388-1396, Docket No. APHIS-2009-0035), we removed lists of regions classified with respect to certain animal diseases and pests from those regulations. The lists are now posted on APHIS' Web site, rather than published in the Code of Federal Regulations.

Accordingly, the proposed addition of Estonia, Hungary, Slovakia, and Slovenia to the APHIS-defined European CSF region, the proposed additions of Estonia, Slovakia, and Slovenia to the list of regions APHIS considers free of SVD, and the proposed addition of Slovakia and Slovenia to the list of regions APHIS considers free of FMD and rinderpest do not need to be finalized through rulemaking. Instead, this preamble provides notice that we are amending the lists on APHIS' Web site ([http://www.aphis.usda.gov/import\\_export/animals/animal\\_disease\\_status.shtml](http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml)). Copies of the lists are also be available via postal mail, fax, or email upon request to the Sanitary Trade Issues Team, National Center for Import and Export, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

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<sup>4</sup> See <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0035>.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes described above.

#### Executive Order 12866 and the Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis identifies hog and pig producers as the small entities most likely to be affected by this action, and considers the effects on domestic prices associated with increased imports of swine, swine semen, pork, and pork products. Based on the information presented in the analysis, we expect that domestic pork producers will experience only a minimal loss of welfare as a result of this action. The analysis provides a basis for the APHIS Administrator's determination that this action will not have a significant economic impact on a substantial number of small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1), or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### National Environmental Policy Act

Environmental assessments and findings of no significant impact have been prepared for this final rule. The environmental assessments provide a basis for the conclusion that the importation of swine, swine semen, pork, and pork products from Estonia, Hungary, Slovakia,

and Slovenia under the conditions specified in the rule will not have a significant impact on the quality of the human environment. Based on the findings of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

The environmental assessments and findings of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessments and findings of no significant impact may be viewed on the Regulations.gov Web site.<sup>5</sup> Copies of the environmental assessments and findings of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

#### Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

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<sup>5</sup> Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0043>. The environmental assessments and findings of no significant impact will appear in the resulting list of documents.

List of Subjects in 9 CFR Part 98

Animal diseases, Imports.

Accordingly, we are amending 9 CFR part 98 as follows:

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

1. The authority citation for part 98 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701;  
7 CFR 2.22, 2.80, and 371.4.

§ 98.38 [Amended]

2. Section 98.38 is amended as follows:

a. In the introductory text, by removing the words “, except as noted in paragraph (h) of this section with regard to swine semen imported from Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom”.

b. By removing paragraph (h).

c. By redesignating paragraph (i) as paragraph (h).

d. In newly redesignated paragraph (h), by removing the words “through (h)” and adding the words “through (g)” in their place.

Done in Washington, DC, this 11<sup>th</sup> day of December 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

